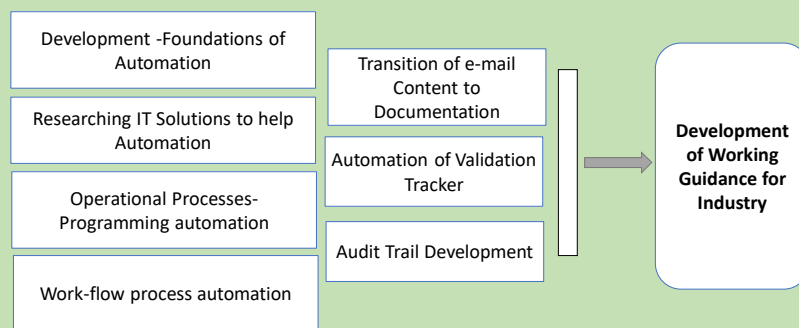
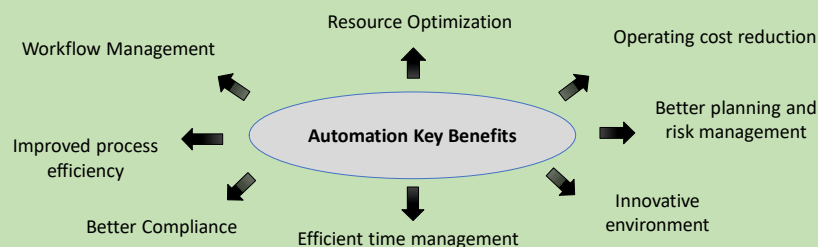


PP12: Clinical Reporting Automation: Are your Processes Ready for it?

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Abstract: One aspect of Data Engineering is looking for ways to incorporate automation. In order to decide what pieces of programming work can be automated, programmer needs to first look holistically at programming processes and standards. This poster discusses the vision of automation sub-team within the data Engineering stream at educating for the Future project at PHUSE. It also offers a guideline to readers on how to incorporate automation rather than explaining what to do in their particular- programming environment. The programmer can use the clearly defined processes and standards to look for automation. The automation doesn't need to be comprehensive around the programming work in a study/submission. Small components can be automated which can save time/effort. In other words, the automation process can preferably be 'evolutionary' as oppose to be 'revolutionary'. This paper will outline the future goals and completed work of 'automation' sub-team of PHUSE 'data engineering' project.

PHUSE Data Engineering Project- Automation Sub-Team Goals and Objectives



Approaches towards Automation: Evolutionary vs Revolutionary

Evolutionary Approach:

In this approach, automation can be done in discrete steps. The principles of automation can be applied at processes or at process segments. Since small process steps are automated, it poses less risk to sponsor and sponsor may be able to adopt this type of automation easily. The work culture of organization can be oriented to adapt the evolutionary approach.

Revolutionary Approach:

In this approach, a new automated process can be implemented. This could disrupt the current work practices. The success of such automation completely depends on how much effectively and efficiently the automated processes are planned and implemented. If not implemented successfully, this can disrupt the business significantly.

Automation Prerequisites:

Clearly Defined Processes:
Discrete Steps explained through pictorial representation such as flow-charts

Adoption of industry level standardization- Getting the benefit of standardization for automation implementation.

Cases of re-application and reusability of processes:
Implementation of processes and development of use cases.

Skilled human resource:
Skilled work force to implement and monitor the automation process

Availability of tools and application to apply automation: Use of right tools and technology for solving problems

Interoperability of Processes: Fit of robust processes in a broader process cycle.

Cases – Automation in Steps

In clinical data reporting and analysis, can you apply automation? In case of 'evolutionary' approach towards automation, several discrete programming processes can be automated by using combination of right tools, technologies and by designing robust processes. Here are couple of representative cases where automation is conducted in industry:

Auto- annotation of Case Report Forms

Automated log checking

Data extraction scheduler

Periodic re-running of TLGs

E-mail content inclusion in documentation

Management -TLG review comments

Auto-generation of e-mail notices

SDTM Specification checking and revalidation

Pre-and post processing of table presentations

compliance checks- SDTM and Define.xml

Sub-group analysis automation

Auto validation of analysis data.

Conclusion:

Given establishment of robust processes, automation can be applied at various stages of process cycle. As a conclusive thought we would like the readers to look into this thought processes of automation and attempt to improve their productivity. As a part of 'automation' sub-team at PHUSE, we are taking efforts to develop set of tools, techniques and set of guidance for industry so that pharmaceutical and biotech industry can benefit from effective implementation of automation principles on data reporting processes.

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